TURKEY

Recent and planned developments in pharmaceutical policies 2016

Special topic: Pricing and reimbursement policies for biosimilars

DEVELOPMENTS

CHANGES IN PRICING

- *10/07/2015: A new Decision on pricing*
- *11/12/2015: A new Notification on pricing*
- *Reference price will be set annually at 70% of the previous year's average Euro/TR exchange rate*
- *Price reviews will be twice a year.*
- *Price flexibility for locally produced medicines*
- *More price flexibility for medicines subjected to special conditions (blood products, traditional herbal medicinal products, hospital products, non-reimbursed products and products of critical importance in terms of public health)*

CHANGES IN REIMBURSEMENT

- *01/04/2016: Delisting imported pharmaceuticals which have at least 3 generic drugs on the market and have a market share lower than 50% on value, time duration 18 months*
- *10/02/2016: Alternative Reimbursement Commission for high priced medicines*
- *22/02/2016: Adjustments in discounts due to reference price changes*

OTHER CHANGES

- *08/2015: A prioritization commission has been established in TMMDA for marketing authorization. It is planned to give rapid access to first generics, unlicensed and imported medicines etc.*

SPECIAL TOPIC

POLICIES FOR BIOSIMILARS

- *Biosimilars are priced based on external reference price system. When biosimilar enters the market, biosimilar is priced same as the price of original biotechnological product. However, biosimilars are expected to be priced 20% lower than its original reference product with new regulations. There isn't any mandatory tendering system for biosimilars.*
- *Reimbursement procedures of biosimilars are like other medicines. After getting retail price from MoH, company submits to Social Security Institution (SSI) with a dossier consisting of clinical evidence and pharmacoeconomic analyses. Company has to give mandatory discounts to SSI. Reimbursement commission decides whether to reimburse these medicines and determines reimbursement prices.*
- *Doctors are not advised to switch from original biotechnological products to biosimilars. We don't have enough information about switches. Biosimilar substitution in pharmacies is allowed and not mandatory. Substitution is allowed for all patients.*
- *It is planned to give incentives to companies to manufacture biosimilars in Turkey. Some of these biosimilars are now at assessment phase of marketing authorization in Turkish Medicines and Medical Devices Agency (TMMDA). Purpose of this action is to improve manufacturing capacity in Turkey and therefore manage the pharmaceutical budget.*